

May 19, 2014

Tami Eide, Pharm D
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Pharmacy and Therapeutic Supervisor
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Re: Hepatitis C Therapeutic Formulary

Tami Eide, Pharm D

I am writing to you regarding the up in coming Formulary consideration for Hepatitis C Drug class approval for Idaho Medicaid. I am the only board certified Hepatologist in the state with over 17 years of experience encompassing treatment of several thousand Hepatitis C patients as well as participation in many of the landmark research trials in Hepatitis C over the last decade. I want to voice my opinion on this drug class to aid the board in their decision to make available the current standard of care for Hepatitis C therapy options.

As you are aware, there are an estimated 5 million individuals infected with Hepatitis C in the United States. 75% of these patients already have the disease for greater than 20 years putting them at great risk of cirrhosis. In fact, studies have shown that "baby boomers" infected with Hepatitis C have a cirrhosis prevalence of 20-30%. Unfortunately, most of these individuals are not diagnosed or properly stage as yet, let alone been treated. In fact, only approximately 1 million patients with Hepatitis C have been offered therapy to date in the United States. Without urgent therapy, these advance liver disease patients will progress to decompensated cirrhosis over the next few years. Once decompensated, these patients will begin utilizing vast medical resources including lab testing, imaging, endoscopic evaluation, and multiple medications to manage their complications of liver disease, as well frequent hospitalizations, liver transplantation and management of liver cancer associated with Hepatitis C. In addition, patients with Hepatitis C are also at risk of multiple non-liver related morbidities including: Cryoglobulinemia with associated arthritis and neuropathy, Membranous Proliferative Glomerulonephritis, and Lymphoma. Moreover, all of these later complications of Hepatitis C are independent to stage of fibrosis and can occur at any duration of infection including within the first 10 years of infection (long before progressive scarring of the liver).

Thus, treatment of Hepatitis C with the intent towards achieving the highest likelihood of cure is of the utmost importance. In December of 2013, the breakthrough drug called Sofosbuvir (HCV polymerase inhibitor) was approved by the FDA. This first in class drug is utilized in combination with Ribavirin with or without Pegylated Interferon depending on Genotype for 12-24 weeks with cure rates between 80-95%. These results are far superior to any drug regimen to date. Moreover, it is well tolerated with few side effects and easy to administer in its once daily oral pill. As you are aware, these regimens are quite costly but the cost savings for preventing decompensated cirrhosis as well as non-liver related morbidities will more than make up for the upfront expense to Idaho Medicaid. Moreover, future regimens will only become more expensive as they will all be Interferon free.

Therefore, I want to urge the Medicaid Pharmacy Board to consider adding Sofosbuvir based regimens to the Medicaid Patient Formulary regardless of fibrosis stage or current complications of their liver disease as per FDA package insert. This is in the best interest of our patients as well as the state health care system.

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